



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1129]

Jennings Ryan Staley: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Jennings Ryan Staley for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Staley was convicted of one felony count under Federal law for Importation Contrary to Law. The factual basis supporting Mr. Staley's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Staley was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. Mr. Staley provided notice to FDA that he acquiesced to the debarment; FDA received that notice on October 6, 2022. As such, his debarment commenced on the date FDA was notified of acquiescence.

DATES: This order is applicable October 6, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4144), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On May 27, 2022, Mr. Staley was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Southern District of California, when the court accepted his plea of guilty and entered judgment against him for the offense Importation Contrary to Law, in violation of 18 U.S.C. 545 and 2. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Plea Agreement in Mr. Staley's case, filed July 16, 2021, as a licensed medical doctor and the proprietor of Skinny Beach Med Spa, Mr. Staley sold "treatment packs" for COVID-19 to members of the public in March and April 2020 in Southern California. Mr. Staley marketed these treatment packs by making statements about the efficacy of the drugs the packs included. For example, Mr. Staley told an undercover agent from the Federal Bureau of Investigation, who posed as a prospective patient, that hydroxychloroquine and mefloquine would cure COVID-19 "one hundred percent" and would provide at least 6 weeks of immunity. Mr. Staley also stated that hydroxychloroquine was a "magic bullet," an "amazing weapon," "almost too good to be true," an "amazing cure," and a "miracle cure" for COVID-19.

To obtain hydroxychloroquine for use in his COVID-19 treatment packs, Mr. Staley contacted merchants in China who could purportedly supply bulk quantities of the drug, including one merchant who could supposedly import kilogram quantities of hydroxychloroquine powder. In Mr. Staley's correspondence with this merchant, he agreed that the merchant would deliberately mislabel the shipment of hydroxychloroquine powder as "yam extract" to fool U.S. Customs and Border Protection (CBP) agents and ensure that the shipment would not be rejected

or delayed. In Mr. Staley's plea agreement, he admitted that by mislabeling what he believed to be 12 kilograms of hydroxychloroquine powder as yam extract in violation of 18 U.S.C. 541, he knowingly and willfully intended to deceive CBP and cause the importation of merchandise into the United States upon a false classification of its quality or value. It is immaterial under 18 U.S.C. 541 that the shipment ultimately contained baking soda rather than hydroxychloroquine.

As a result of this conviction, FDA sent Mr. Staley, by certified mail, on September 8, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Staley's felony conviction under Federal law for Importation Contrary to Law, in violation of 18 U.S.C. 545 and 2, was for conduct relating to the importation into the United States of a drug or controlled substance because, in order to defraud CBP, he knowingly and willfully intended to cause the mislabeling and importation of 12 kilograms of what Mr. Staley believed to be hydroxychloroquine powder upon a false classification of its quality or value in violation of 18 U.S.C. 541.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Staley's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Staley of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Staley received the proposal and notice of opportunity for a hearing. Through his attorney, Mr. Staley sent a memorandum to FDA, dated September 26, 2022, wherein he stated that he acquiesced to the proposed debarment. FDA received the memorandum on October 6, 2022. In accordance with section 306(c)(2)(B) of the FD&C Act, Mr. Staley's period of debarment shall commence on the

date FDA received notice he acquiesced to the debarment, which was October 6, 2022 (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Jennings Ryan Staley has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Staley is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective October 6, 2022. Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Staley is a prohibited act.

Any application by Mr. Staley for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2022-N-1129 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: November 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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